

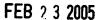
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## **BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/744,506 Filing Date: \*\*\*

Appellant(s): LANZENDORFER

HOWARD LEE For Appellant

**EXAMINER'S ANSWER** 

This is in response to the appeal brief filed August 24, 2004.

(1) Real Party in Interest Application/Control Number: 09/744,506 Page 2

Art Unit: 1617

A statement identifying the real party in interest is contained in the brief.

# (2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

### (3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

#### (4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

#### (5) Summary of Invention

The summary of invention contained in the brief is correct.

#### (6) Issues

The appellant's statement of the issues in the brief is correct.

#### (7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because, while applicants seek to group the composition and method claims separately, these claims are rejected under same set of references.

#### (8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

#### (9) Prior Art of Record

US Pat. No. 4,664,910

CASERIO ET AL.

05-1987

US Pat. No. 6,103,246

TISDALE ET AL.

08-2000

### (10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 9, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caserio et al. (US 4664910) ("Caserio" hereunder) in view of Tisdale et al. (US 6103246) ("Tisdale").

Caserio teaches a topical composition for skin or hair which comprises 0.1-20 % of cholanic acid derivatives and a powder absorbent. Optionally, water and/or other liquid carriers can be incorporated in the composition. The reference teaches that lithocholic acid, deoxdycholic acid, and cholic acid are preferred cholanic acid derivatives. Emollients, propellants, organic solvents, humectants, and thickeners are taught as cosmetically acceptable carriers. The reference also teaches to add antioxidants. Example 5 shows a composition comprising 5% taurocholic acid and cosmetic auxiliaries. See abstract; col. 1, line 66-col. 2, line 37; col. 3, lines 64-66; col. 4, lines 6-11; col. 6, line 59 – col. 7, line 11; col. 8, line 13-col. 8, line 50.

While the reference lacks specific teachings of the weight of the antioxidants to be used, examiner notes that, since the general condition of using antioxidants in the cosmetic composition is taught, discovering the optimum or workable ranges involves only routine skill in the art because of the expectation of achieving a composition with

optimum antioxidant effects. The reference in fact discloses a composition in Example 6 comprising 1.03 % of pigment and antioxidant.

Regarding the phrase "a barrier strength effective amount" in instant claim 20, examiner respectfully points out that the instant invention requires the same amount of a bile acid or salt as the prior art uses, which is 0.01-0.5 %. For claims 19-20 which are directed to method of applying 0.01-0.5 % of a bile acid of its salt, examiner asserts that the claimed method is practiced by the topically application of the bile acid-containing prior art composition. Any properties exhibited by or benefits provided the compositions are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicants disclose and/or claims are necessarily present.

Caserio fails to teach encapsulated forms.

Tisdale teaches that liposomes (encapsulated preparation forms) penetrate into the deep underlyling layers of the skin where they deliver their active agents in a time-release action. See col. 2, lines 38 –59. The reference also teaches that liposomes encapsulate "a portion of the solution" in which the liposome is found. See instant claim 18.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Caserio invention by formulating the liquid composition in Caserio in the form of liposomes as taught by Tisdale because of the

expectation of successfully achieving a cosmetic composition with enhanced skin penetration and time-released action.

Claims 22-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caserio and Tisdale as applied to claims 8, 9, 18-21 above, and further in view of Pittrof et al. (US 5376646).

Caserio and Tisdale fail to teach vitamin E.

Pittrof teach cosmetic compositions comprising a cholanic acid and a lipid.

Examples show a micelle solution mixed with 2% tocopherol and sodium glycocholate.

See col. 6, line 60 – col. 7, line 12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding the tocopherol acetate as taught by Pittrof to the composition because the Caserio reference teaches that antioxidants are added to its composition, and Pittrof teaches tocopherol acetate as an antioxidant that can be combined with bile acid salt. Thus, the skilled artisan would have been motivated to look to Pittrof for antioxidants that are combinable with bile acid salts.

## (11) Response to Argument

Claims 8, 9, 18, and 21 were properly rejected under 35 U.S.C. § 103 (a) in view of the collective teachings of the Caserio and Tisdale references.

Applicants assert that claimed the prior art references were not considered as a whole. Specifically, applicants assert that the examiner's rejection lacks "a reason why one of ordinary skill in the art would combine the references given the respective teachings of Caserio and Tisdale".

Applicants assert a skilled artisan would not have understood why adding the properties of enhanced skin penetrability and time-release action to the invention of Caserio would have been obvious. In response, examiner respectfully points out that the rejection is made from the perspectives of one of ordinary skill in the art, based on the objective teachings of the references of what would have been obvious to a skilled artisan at the time of the present invention. Tisdale teaches that liposomes are desired specifically because of the deep penetration of the cosmetic active ingredients to the underlying layers and skin so that the actives are delivered in a time-release action. The reference clearly teaches that the enhanced delivery of cosmetic actives to the skin layers is desired in cosmetic application, which is the examiner's cited reason to make the Caserio composition into a liposomal formulation. Applicants' argument that such explanation is not sufficient to form a motivation to make a liposomal formulation is unpersuasive.

Applicants argue that Tisdale teaches away from combining with the teachings of Caserio. Specifically, applicants assert that Tisdale teaches "inconsistency in providing enhanced skin penetration activity" and the "cost of using liposomes". Examiner respectfully points out that these teachings of the disadvantage of liposome do not constitute teaching away. Rather, the reference merely teaches a nonpreferred embodiment at most. It is well known in patent law that "the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." See MPEP § 2123, quoting In re Heck, (citation omitted).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art. See Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 U.S.P.Q. 2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). It is also held that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. The court in In re Susi also held that "a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See 440 F.2d 442, 169 U.S.P.Q. 423 (C.C.P.A. 1971). In this case, the reference teaches that liposomal formulations are known in the art. The specific benefits of the enhanced skin penetration and the time-release action of cosmetic actives are also taught. A cosmetic liposomal formulation does not become patentable merely because it is taught to be partially effective and costly.

Applicants also assert that the reference suggests using liposomal formulation only in combination with emu oil. Examiner respectfully points out that a skilled artisan would have reasonably understood that the liposomal formulation is applicable in cosmetic formulation in general. Applicants assert that it would be "nonsensical" to add an oil to the Caserio composition which is intended to remove sebum and sweat. Adding an oil to the Caserio composition is not the examiner's cited motivation to combine the references. The ground of the rejection is that making cholanic acid composition in to liposomal formulation as applicants have done would have been obvious to a skilled artisan because then the composition would provide enhanced delivery of the active agent to the skin.

Claims 19 and 20 were properly rejected over Caserio and Tisdale because the claimed method of strengthening the barrier function of the skin is inherently practiced by topically applying the composition of the combined references because the composition comprises the only active ingredient of the present invention.

Applicants assert that the examiner misapplied the holding of <u>In re Spada</u>. See 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). Examiner respectfully disagrees. It is obvious that a composition would exhibit the properties of the compound present therein. The claimed composition merely requires a bile acid or its salt in an encapsulated form. It is obvious that any composition comprising the only claimed compound (i.e., the bile acid or its salt) would have the same property as applicants' composition.

Applicants assert, "the mere presence of one common compound in two different compositions is insufficient to establish that both compositions have the same properties". The argument is unpersuasive. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. See <a href="In re Wiseman">In re Wiseman</a>, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). The court in <a href="Ex parte Obiaya">Ex parte Obiaya</a> also held, "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." See 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, "strengthening the barrier function of the skin" would naturally occur by the prior art method of the topical application of the composition comprising cholanic acid because the property of the compound would be present the composition. Thus, examiner takes the position that evidentiary support to show the claimed

properties of cholanic acid is not necessary because the claimed method is inherently practiced by using the same compound as taught by the prior art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Patent Ekamîv Februarv 14. 2005

Conferees

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